UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

January 3, 2017

DP BARCODE:	435880
MRID:	49989000, 49989001, 49989002, and 49989003
SUBJECT:	CaviCide Bleach
REG. NO.:	46781-RL
DOCUMENT TYPE:	Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
014703	7681-52-9	Sodium Hypochlorite

TEST LAB:	Metrex Research LLC
SUBMITTER:	Scientific & Regulatory Consultants, Inc.
GUIDELINE:	Group A and B Product Chemistry
ORGANIZATION:	AD\PSB\CTT
REVIEWER:	Lynette T. Umez-Eronini
APPROVED BY:	Karen P. Hicks
APPROVED DATE:	December 29, 2016
COMMENT:	This product is for non-food use.

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Antimicrobials Division (AD)

January 3, 2017

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 46781-RL
Product Name: CaviCide Bleach
DP Barcode: 435880

FROM: Lynette T. Umez-Eronini, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Demson Fuller PM #32/Benjamin Chambliss
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Metrex Research

CODE: A540 New Product; Non-Fast Track;

DATE DUE: February 6, 2017

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium Hypochlorite	0.91
Other Ingredient(s):	99.09
Total:	100.00

BACKGROUND:

The consultant, Scientific & Regulatory Consultants, Inc., on behalf of the registrant, Metrex Research has submitted an application for registration of a non-integrated end-use product called CavicCide Bleach. This product is a bleach for disinfecting, cleaning and deodorizing hard non-porous surfaces. The product is for non-food use.

The original data package included:

1. Cover letter from the registrant to EPA, dated August 15, 2016.
2. Application (8570-1), dated August 15, 2016.
3. Basic CSF, dated August 5, 2016 and Alternate #1 CSF, dated August 11, 2016 and November 29, 2016.
4. Formulator's Exemption Statement (8570-27), dated August 15, 2016
5. Certification with Respect to Citation of Data (8570-34), dated August 15, 2016.
6. Data Matrix (8570-36), dated August 15, 2016.
7. Draft label, dated August 15, 2016.

FINDINGS:

1. Alternate CSF #1, dated August 11, 2016 required correction, is obsolete and superseded by Alternate #1 CSF, dated November 29, 2016.
2. The nominal concentration of the active ingredient on the Basic and Alternate #1 CSFs, dated respectively August 5, 2016 and November 29, 2016 is consistent with the label.
3. Support for wider certified limits for the active ingredient and one of the inert ingredients is provided and found acceptable.
4. All active ingredient sources are EPA registered.
5. All ingredients in this formulation are approved for use in pesticide formulations.
6. Group A product chemistry data requirements applicable to end-use products are met (see MRID 49989002 on Table A below).
7. Group B product chemistry data requirements applicable to end-use products are met (see MRID 49989002 and 49989003, on Table B below), with the exception of OPPTS 830.6314 (Oxidation/Reduction: Chemical Incompatibility), OPPTS 830.7000 (pH), OPPTS 830.7100 (Viscosity), and OPPTS 830.7300 (Density).
8. MRID 49989001 shows the liquid solution on CaviWipes Bleach is identical to the liquid in CaviCide Bleach and makes reference to MRID 49921702. Studies (see MRID 49921702) conducted on the CaviWipes Bleach (solution) are bridged for product chemistry studies for CaviCide Beach. Hence, data requirements for OPPTS 830.6314 (Oxidation/Reduction: Chemical Incompatibility), OPPTS 830.7000 (pH), OPPTS 830.7100 (Viscosity), and OPPTS 830.7300 (Density) are met in MRID 49921702 (see Table B below).
9. Support (see MRID 49989002). for wider certified limits for the active ingredient based on storage stability results is provided and found acceptable.

10. Support (see MRID 49989002) for higher upper certified limit for one of the inert ingredients is provided and found acceptable.

CONCLUSION:

Product Science Branch of Antimicrobials Division finds the Basic and Alternate #1 CSFs, dated respectively August 5, 2016 and November 29, 2016 to be acceptable and Group A and B Product Chemistry data requirements have been met.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [X] No [ ]
- Are all TGAIs used registered? — Yes [ ] No [X]
- Integrated formulation system — Yes [ ] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [ ] No [X]

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient	NC(%)	LCL(%)	UCL(%)
Sodium Hypochlorite	0.91	0.82	1.40

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	49989002
830.1600 Description of Materials	A	49989002
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A	49989002
830.1670 Formation of Impurities[4]	NA	
830.1700 Preliminary Analysis[5]	NA	
830.1750 Certified Limits[6]	A	49989002
830.1800 Enforcement Analytical Method[7]	A	49989002
830.1900 Submittal of Samples	A	49989002

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		
830.6303 Physical State	A	Liquid.	49989001
830.6304 Odor	N/A		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	See Table below. **	49921702
830.6315 Flammability/ Flame Extension	A	Waiver. Not required. Water constitutes > 95% of the formulation, all the ingredients in formulation has fire/flammability classification 0 (zero). Non-Flammable – water based product	49989002
830.6316 Explodability	A	Waiver. Not required since the product is not considered potentially explosive.	49989002
830.6317 Storage Stability (14-Day Accelerated Study)	A	Time, day [$NaClO_3$], % 0 1.37 14 1.20 Concentration of active ingredient falls within upper and lower certified limits	49989003
830.6319 Miscibility[1]	A	Waiver. Not required since the product is not an emulsifiable liquid and is not to be diluted with petroleum solvents.	49989002
830.6320 Corrosion Characteristics (14-Day Accelerated Study)	A	No corrosion of the packaging, no leakage, no label discoloration, no rust at the seam.	49989003
830.6321 Dielectric Breakdown Voltage	A	Waiver. Not required since the product is not intended for use around electrical equipment.	49989002
830.7000 pH[2]	A	10.44	49921702
830.7050 UV/Visible Absorption	NA		

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7100 Viscosity	A	Kinematic viscosity – 1.2437 centistokes 20±2°C 0.8878 centistokes 45±5°C Dynamic Viscosity – 1.2872 centipoise 20±2°C 0.9189 centipoise 45±5°C .	49921702
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	1.0350 g/ml	49921702
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

** Table of Chemical Incompatibility Results

Test Substance: CaviWipes Bleach (solution) Lot# 16-1069RDO				
Material	**Initial Temperature**	**Initial Observations/ Reaction**	**Final Temperature**	**Final Observations/ Reaction**
Water (Reactivity Evaluation with Water)	22.5°C	No change	22.5°C	No change
Monoammonium phosphate (Reactivity with Fire Extinguishing Agents)	22.0°C	Evolution of gas, bubbling and foaming	26.5°C	No change
Turpentine (Chemicals Intended for Household Use)	22.5°C	Immiscible – no reaction	22.5°C	No change
$KMnO_4$ (For Oxidizing agents)	22.4°C	No change	22.5°C	Brown precipitate forming

$KMnO_4$ = Potassium Permanganate

CONFIDENTIAL ATTACHMENT

Pages 12-24 - *Confidential Statements of Formula may be entitled to confidential treatment*